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10/781,543	02/17/2004	Moshe Flashner-Barak	1662/63202	3365

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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,543	FLASHNER-BARAK ET AL.	
	Examiner	Art Unit	
	LESLIE A. ROYDS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 5-24* is/are pending in the application.

4a) Of the above claim(s) *7-19 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,20,22-24* is/are rejected.

7)☒ Claim(s) *5,6 and 20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *27 March 2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1 and 5-24 are presented for examination.

Applicant's Amendment filed November 3, 2008 was received and entered into the present application, but was non-compliant pursuant to the Notice dated February 11, 2009. Applicant's supplemental amendment filed March 11, 2009 has been received and entered into the present application.

Applicant's Information Disclosure Statement (IDS) filed March 27, 2009 has been received and entered into the present application. As reflected by the attached, completed copy of form PTO/SB/08A (two pages total), the Examiner has considered the cited reference.

Claims 1 and 5-24 are pending. Claims 2-4 are cancelled. Claims 22-24 are newly added. Claims 1, 5-6 and 20 are amended. Claims 7-19 and 21 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b).

Applicant's amendments to the instant claims to remove "cyclosporin" as a possible option of at least one poorly bioavailable drug to be used renders the previous prior art and obviousness-type double patenting rejections directed to this particular specie of poorly bioavailable drug **moot**. Applicant is notified that examination has been expanded herein to the species of ketoprofen as the at least one poorly bioavailable drug for use in the instantly claimed composition.

Applicant's arguments, filed March 11, 2009, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and objections are either reiterated or newly applied. They constitute the complete set of rejections and objections presently being applied to the instant application.

Objection to the Claims (New Grounds of Objection)

Claims 5-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 20 is objected to for failing to define the acronym "AUC" at its first occurrence in the claims (i.e., the composition claims that are presently under examination).

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement, New Matter (New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Present claim 22 is directed to the composition of instant claim 20, wherein the average AUC of said composition is at least 10% more than the average AUC of a non-menthol containing formulation.

In particular, the specification and claims as originally filed fail to provide adequate written description for the newly added limitation directed to wherein the average area under the curve of *any* concentration of said composition is at least 10% more than the average AUC of a non-menthol containing formulation (claim 22).

MPEP §2163 states, "The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must

convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test of sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983))…Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991)."

Applicant discloses at p.4, l.25-31, "In one embodiment, the amount of menthol sufficient to increase the drug's bioavailability may be from about 20% to about 99% by weight, preferably, the menthol may be present in an amount of about 60% to about 95% by weight of the composition. Alternatively, the amount of menthol may be sufficient to increase the oral bioavailability of the drug by an increase of about 10% or more in the average area under the blood or plasma concentration versus time curve (AUC) when compared to the average AUC for a non-menthol containing composition of the drug."

However, such disclosure of an increase of about 10% or more in the average area under the *blood or plasma concentration* versus time curve as compared to the average AUC for a non-menthol containing formulation fails to provide adequate written support to now claim an increase of at least 10% or more for the average AUC for *any concentration* (i.e., blood, plasma, serum, urine, etc.) as compared to the average AUC for a non-menthol containing formulation. This is a clear broadening of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure because the original disclosure of an at least 10% increase in the average AUC for blood or plasma concentration(s) as compared to the average

AUC of a non-menthol containing formulation fail to provide written support to now claim that the at least 10% increase occurs in the average AUC for *any concentration* (i.e., blood, plasma, serum, urine, etc.) as compared to the average AUC for a non-menthol containing formulation. It is clear, therefore, that Applicant was not in possession of the concept of an at least 10% increase in the average AUC of *any concentration* (as compared to the average AUC of a non-menthol formulation), but rather was solely in possession of the concept an at least 10% increase in the average area under the blood or plasma concentration time curve (as compared to the average AUC of a non-menthol formulation).

As stated in MPEP §2163, "The subject matter of the claim need not be described literally (i.e., using the same terms of *in haec verba*) in order for the disclosure to satisfy the description requirement." However, considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the limitation directed to wherein the average area under the curve of *any* concentration of said composition is at least 10% more than the average AUC of a non-menthol containing formulation (claim 22).

Accordingly, the claim is considered to lack sufficient written description and is properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 102 (New Grounds of Rejection)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 20 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Rubin et al. (U.S. Patent Application Publication No. 2001/0049363; December 2001).

Rubin et al. teaches oral compositions for treating gingivitis, wherein the composition comprising at least one non-steroidal anti-inflammatory drug, thymol, methyl salicylate, menthol and eucalyptol and may be provided in the form of, e.g., a mouthwash or toothpaste (i.e., and, thus, "suitable for oral administration" as recited in instant claim 1). Rubin et al. further teaches a preferred embodiment of the invention, wherein the composition comprises about 0.001 to about 2 wt% NSAID; about 0.02 to about 0.1 wt% thymol; about 0.03 to about 0.08 wt% methylsalicylate; about 0.03 to about 0.06 wt% menthol; and about 0.07 to about 0.11 wt% eucalyptol (p.1, para.[0014-0019]). Rubin et al. discloses that the NSAID used in the composition may be, *inter alia*, propionic acid derivatives, including, *inter alia*, ketoprofen (p.2, para.[0025-0035]).

Though it is noted that the amount of menthol used in the composition of Rubin et al. (i.e., about 0.03 to about 0.06 wt% menthol; p.1, para.[0018]) is less than "about 20%" as instantly claimed (instant claim 1) or "about 60%" as instantly claimed (instant claim 24), this teaching of 0.03-0.06 wt% menthol is understood to meet Applicant's claimed amount of menthol of "about 20%" (claim 1) or "about 60%" (claim 24) because the term "about" as used in instant claim 1 permits some tolerance both above and below the recited endpoint absent an explicit definition of the degree of variation intended to be encompassed by the term. Where close prior art exists (such as, in this case, Rubin et al.), the burden is on Applicant to establish that the term "about" as used in the instant claims is sufficiently clear to avoid such art. In the instant case, *Applicant has failed to provide a definition of the term "about" in the instant specification, such that there is no indication or hint as to what amount of variation above or below the recited amount would constitute infringement of the instant claims.* There is nothing in the specification, prosecution history or prior art that provides any indication as to what amount of variation is tolerated by the term "about". Absent such information, and further in view of what is actually disclosed by Rubin et al. (i.e., menthol in an amount of 0.03-0.06 wt%), this teaching of Rubin et al. is understood to meet Applicant's claimed amount of "about 20%" (claim 1) or "about 60%" (claim 24), absent factual evidence

to the contrary, and further absent any clear indication in the specification or claims that an amount of 0.03-0.06 wt% would not be encompassed by the variation in and around the claimed endpoint of "about 20%" (claim 1) or "about 60%" (claim 24).

Regarding Applicant's limitations directed to (1) wherein the average AUC of said composition is at least 5% more than the average AUC of a non-menthol containing formulation (claim 20), (2) wherein the average AUC of said composition is at least 10% more than the average AUC of a non-menthol containing formulation (claim 22) or (3) wherein the average AUC of said composition is at least 15% more than the average AUC of a non-menthol containing formulation (claim 23), the pharmaceutical composition of Rubin et al. comprises the identical active agents in an identical physical structure (e.g., a composition suitable for oral administration) in identical amounts to that instantly claimed. Therefore, the composition of Rubin et al. must necessarily possess the same AUC characteristics (as defined in instant claims 20 and 22-23) as that presently claimed whether recognized by the patentee or not because products of identical chemical composition cannot exert mutually exclusive properties when prepared or used in the same manner under the same circumstances. In other words, if the prior art teaches the identical chemical or physical structure of the composition (i.e., same active agents, same physical structure, same amounts, etc.), the properties that Applicant discloses and/or claims must necessarily be present. See MPEP §2112.

In re Best (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation, the burden is shifted to the Applicants to "prove that the subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 592, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of the invention, but only that the subject matter is, in fact, inherent in the prior art reference.

Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.,* 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention"). In the instant case, though Rubin et al. may not expressly teach the average AUC of the disclosed composition versus the average AUC of the disclosed composition without menthol, the prior art to Rubin et al. contains the same active agents as that presently claimed in the same physical structure and in the same amounts, and, therefore, the resultant AUC properties must also be the same, absent factual evidence to the contrary. The burden is now shifted to Applicant to prove that, in fact, Rubin et al. does not possess these same claimed characteristics.

Response to Applicant's Arguments

Applicant provided arguments regarding the interpretation of the word "about" as it applied to the previously pending rejection over Benet et al. Even though such a rejection has been withdrawn and a new rejection over Rubin et al. (see *supra*) has been set forth as a result of Applicant's amendments, the remarks regarding the term "about" apply equally to the new rejection and are addressed below.

Applicant traverses the interpretation of the word "about" as used in, e.g., instant claim 1 or 24, stating that the Office's interpretation is so stretched that it does not propose any evidence in fact or law to support this interpretation. Applicant asserts that 6% is not 20% or even about 20% as claimed, but rather is 300% the value cited as anticipatory. Applicant insists the term "about" is proper in a claim and "does not allow the Office to interpret the term for any numerical limitation, much less find grounds to argue an indefiniteness rejection within an anticipatory rejection as the Office has done here." (p.8, Remarks)

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, though Applicant feels that the Office's interpretation is too stretched to be a plausible interpretation of the word "about", Applicant is reminded that the instant specification fails to explicitly, precisely and definitively define, on the record, the metes and bounds of the term "about" such that it would be clear to one of skill in the art the degree of variation that is intended to be present in and around the specified endpoint(s), i.e., how much above or how much below 20% would be permitted by the instant claims. As a result, although Applicant may not intend for the claims to read upon, e.g., 6% menthol (as in the previous reference to Benet et al.), or less as disclosed in Rubin et al., it remains that the specification and claims as originally filed fail to clearly set forth any limiting definition such that it would have been plainly apparent to the skilled artisan that such an amount of menthol was excluded by the instant claims. Absent such a definition to direct examination, the Examiner is charged with the responsibility of assigning the broadest reasonable interpretation to the claimed invention in accordance with MPEP §2111, which states, "During patent examination, the pending claims must be 'given their broadest reasonable interpretation consistent with the specification.' The Federal Circuit's *en banc* decision in *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) expressly recognized that the USPTO employs the "broadest reasonable interpretation" standard: The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 [70 USPQ2d 1827] (Fed. Cir. 2004). Indeed, the rules of the PTO require that application claims must 'conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.' 37 CFR 1.75(d)(1). 415 F.3d at 1316, 75 USPQ2d at 1329. See also *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Applicant always has the opportunity to amend the claims during

prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969).'"

Applicant's attempts to impute a specific definition to the term "about" where one has clearly not been provided so as to avoid the Examiner's broadest most reasonable interpretation of the term and/or attempts to allege that the claims exclude certain embodiments found in the prior art are clearly unpersuasive because Applicant has not pointed to any disclosure that would support his assertions that the term "about" as used in the instant claims avoids the cited prior art. Furthermore, Applicant is mistakenly under the assumption that the Examiner must provide "evidence in fact or law to support this interpretation" of the term "about". In fact, where close prior art exists (such as, in this case, Rubin et al.), *the burden is on Applicant* to establish that the term "about" as used in the instant claims is sufficiently clear to avoid such art, not the Examiner. This is because the instant specification and claims as originally filed provide no direction as to how Applicant intends for this term to be understood in the context of the claimed invention. Applicant has not met his burden of establishing that the term "about" as used in the instant claims is sufficiently clear so as to exclude the prior art embodiments and, therefore, has not persuasively argued that the prior art of record does not anticipate the instant claims.

Lastly, the Office does not disagree that the term "about" may be used in a claim. However, the issue at hand is that Applicant has provided no direction as to the amount of variation in and around the claimed endpoints that is tolerated by the term "about" and, thus, has not established what values are included or excluded from the instant claims such that it would be clearly apparent to one of ordinary skill in the art what prior art embodiment would or would not read on the instantly claimed invention. Therefore, Applicant's allegation that the Examiner has "stretched" the definition of the term to include values lower than 20% (such as the 6% value disclosed by Benet et al.) is clearly unimpressive because Applicant has not provided any specific definition upon which he can rely to establish that 6% menthol is

well outside the amount of variation intended to be present within the claimed invention by use of the term "about".

Conclusion

Rejection of claims 1, 20 and 22-24 is proper.

Claims 5-6 are **objected** to for depending from a rejected base claim.

Claims 7-19 and 21 are **withdrawn** from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE A. ROYDS whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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May 27, 2009

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